How to Implement an Effective Pathogen Environmental Monitoring Program

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### U.S. FoodNet Disease Surveillance Data - CDC

<table>
<thead>
<tr>
<th>Pathogen</th>
<th>Incidence / 100,000 population - 2008</th>
<th>Incidence / 100,000 population - 2007</th>
<th>% Change from 2007</th>
<th>% Change from 1996 - 1998</th>
<th>Healthy People 2010 Goal</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Salmonella</strong></td>
<td>16.20</td>
<td>14.92</td>
<td>+ 8.58% (NS)</td>
<td>0%</td>
<td>6.80</td>
</tr>
<tr>
<td><strong>Campylobacter</strong></td>
<td>12.68</td>
<td>12.79</td>
<td>- 0.86% (NS)</td>
<td>- 32%</td>
<td>12.30</td>
</tr>
<tr>
<td><strong>Shigella</strong></td>
<td>6.59</td>
<td>6.26</td>
<td>+ 5.27% (NS)</td>
<td>- 40%</td>
<td>NA</td>
</tr>
<tr>
<td><strong>Cryptosporidium</strong></td>
<td>2.25</td>
<td>2.67</td>
<td>+15.73% (NS)</td>
<td>0%</td>
<td>NA</td>
</tr>
<tr>
<td><strong>STEC O157</strong></td>
<td>1.12</td>
<td>1.20</td>
<td>+ 6.67% (NS)</td>
<td>- 25%</td>
<td>1.00</td>
</tr>
<tr>
<td><strong>STEC non – O157</strong></td>
<td>0.45</td>
<td>0.57</td>
<td>- 0.21% (NS)</td>
<td>NA</td>
<td>NA</td>
</tr>
<tr>
<td><strong>Yersinia</strong></td>
<td>0.36</td>
<td>0.36</td>
<td>0%</td>
<td>- 48%</td>
<td>NA</td>
</tr>
<tr>
<td><strong>Listeria</strong></td>
<td>0.29</td>
<td>0.27</td>
<td>+ 0.07% (NS)</td>
<td>- 36%</td>
<td>0.24</td>
</tr>
<tr>
<td><strong>Vibrio</strong></td>
<td>0.29</td>
<td>0.24</td>
<td>+ 20.83% (NS)</td>
<td>+ 47%</td>
<td>NA</td>
</tr>
<tr>
<td><strong>Cyclospora</strong></td>
<td>0.04</td>
<td>0.03</td>
<td>+ 33.33% (NS)</td>
<td>NA</td>
<td>NA</td>
</tr>
</tbody>
</table>
U.S. FoodNet Disease Surveillance Data - CDC

• “The lack of recent progress toward the national health objective targets and the occurrence of large multistate outbreaks point to gaps in the current food safety system and the need to continue to develop and evaluate food safety practices as food moves from the farm to table.”

• “Enhanced and food-specific measures are needed to:

1) control or eliminate pathogens in domestic and imported food;

2) reduce or prevent contamination during growing, harvesting, and processing; and

3) continue the education of restaurant workers and consumers about risks and prevention measures.”

• “In particular, continued efforts are needed to understand how contamination of fresh produce and processed foods occurs and develop and implement measures that reduce it.”

• “More outbreaks can be recognized and their causative foods identified with rapid and complete subtyping of pathogens and with rapid standardized interviews of ill persons and appropriately selected controls.”

Managing the Food Safety Landscape

• Progress continues to be difficult as shown by ongoing events that have shaken consumer confidence in the safety of the U.S. food supply

• Major outbreaks continue in the U.S. resulting in a continuing stream of costly product recalls:
  - Peanut butter/peanut products (PCA) $1+ billion
  - Pot pies (*Salmonella*) $20+ million
  - Peanut butter – 2007 (*Salmonella*) $66+ million
  - Spinach (*E. coli* O157:H7) $25-50 million
  - Pet food (melamine) $40+ million
  - Chili sauce (botulism) $35 million
ICMSF Recommendations for Minimizing Product Recontamination

- The International Commission on Microbiological Specifications for Foods (ICMSF) recognizes that, while it is not possible to prevent the introduction of pathogens into food processing facilities, it is crucial to minimize their presence:
  - **Raw agricultural commodities** need physical separation through plant design and layout in order to minimize entry of pathogens into processed product areas
  - **Food handlers** and maintenance personnel can be a source of food contamination and must be trained in proper hygiene principles
  - **Personal clothing**, in particular shoes, can transfer pathogens from one area to another and must be controlled
ICMSF Recommendations for Minimizing Product Recontamination

- **Air and water** must be controlled. Compressed air filters can be a source of contamination if not properly maintained and water aerosols can disperse microorganisms throughout the facility if not controlled.

- **Insects and other pests** can act as vectors of pathogen transmission in the food manufacturing plant if not properly controlled.

- **Transport equipment** such as racks, trolleys, carts, forklifts and similar equipment can be important vectors for transferring microorganisms throughout a facility and should be limited to use in specific areas.
Factors That Must Be Controlled in Nut Processing Facilities

• Dust control is critical to limiting the spread of salmonellae throughout the facility

• The introduction of moisture into the environment must be minimized to the greatest extent possible
  – The combination of dust and water can lead to the growth of salmonellae and other pathogens to high levels in the environment that can then be easily spread throughout the facility
Factors That Must Be Controlled in Nut Processing Facilities

• Raw and pasteurized product should be physically segregated to minimize the potential for recontamination

• Traffic flow (both people and materials) throughout the plant should be controlled

• Cleaning and sanitation procedures need to be effective and validated
Salmonella Control Equation

Traffic patterns + GMPs + Dust/Moisture Control + Sanitary design + Sanitation procedures = Salmonella Control

Mismanagement of any of the components may increase the risk of cross-contamination.
GMA’s 7 Elements for *Salmonella* Control In Low-Moisture Products

- The Grocery Manufacturers Association (GMA) has outlined seven elements which are consistent with the *Salmonella* control equation that need to be applied to control salmonellae in low-moisture foods:
  
  1. Prevent ingress or spread of *Salmonella* in the processing facility
  
  2. Enhance the stringency of hygiene practices and controls in the Primary *Salmonella* Control Area (PSCA)
  
  3. Apply hygienic design principles to building and equipment design
GMA’s 7 Elements for *Salmonella* Control In Low-Moisture Products

4. Prevent or minimize growth of *Salmonella* within the facility

5. Establish a raw materials/ingredients control program

6. Validate control measures to inactivate *Salmonella*

7. Establish procedures for verification of *Salmonella* controls and corrective actions

- Focusing on the elements of the *Salmonella* control equation and the seven control elements outlined in the GMA document with significantly reduce risk to the product and the consumer

  – Conversely, ignoring these principles will greatly increase your risk of a *Salmonella* recontamination event and present increased risk to your franchise and your consumers
Principles of a PEM Program

- Microbiological monitoring of the food processing environment can be performed to meet a number of objectives
  - Verifying the effectiveness of cleaning and sanitation practices
  - Determining the frequency required for cleaning and sanitation
  - Determining the presence of foodborne pathogens or their indicators in the environment and on equipment
  - Determining environmental sources of spoilage organisms
  - Determining the frequency required for special maintenance procedures (e.g. changing air filters)
  - Evaluating the hygienic design and fabrication of food processing equipment and facilities
Principles of a PEM Program

- It is more practical and reliable to monitor the processing environment than to rely solely on finished product testing.

- Environmental monitoring has a multitude of benefits:
  - Provides dynamic information on the state of a processing line and the PSCA.
  - Can be used for identifying harborage niches.
  - Can be used for trend analysis and measuring effectiveness of interdictive actions.
  - Is flexible and can be tailored to specific situations.

- An effective PEM program is a measure of how well your facility is managing all of the elements of the *Salmonella* control equation.
Principles of a PEM Program

- Implementing a PEM program may, at first, seem like a daunting undertaking

- However, it is a logical, systematic approach that can be developed in fairly short order but will take time to completely reach “steady state”
  - It is a data driven “seek and destroy” program – “follow the data”

- You want to encourage employees to find the pathogen or its indicator if there
  - Only then can you react and do something about it
Principles of a PEM Program

• A PEM program is specific to the individual facility under consideration and specific to the individual operations within the facility
  – Other than the common principles discussed, there is no “one size fits all” program

• If you do not have a food safety professional on staff experienced with PEM programs, it is highly recommended that you make use of an experienced outside expert or process authority to guide you through the process
Getting Started With Your PEM Program

- The first order of business is to assemble your team that will develop and implement the PEM program

- You should designate one person responsible to be the team leader and depending on the size of your operation, this may be their only job

- You should assemble a cross functional team familiar with your operation to help identify potential areas of risk or concern, including
  - Quality manager
  - Plant or corporate microbiologist
  - Sanitation supervisor or operators
  - Operations manager
  - Plant engineer
  - Maintenance supervisor
  - Line supervisor
  - Warehouse supervisor
Getting Started With Your PEM Program

• Once your PEM team is assembled it is important to understand your process flow with an emphasis on identifying potential points of product recontamination
  – Blueprints and flow diagrams are very useful aids in this process, but it is absolutely essential that you walk the plant floor to determine areas where the product may be vulnerable to recontamination after the lethality step

• It is also valuable to conduct environmental monitoring in raw areas, but you need to understand that you will occasionally find *Salmonella* in those areas
  – Monitoring in these raw areas can provide insight into the potential of *Salmonella* to be present and the potential to be spread into the PSCA
Hygienic Zone Assessment

• Your team should conduct a hygienic zone assessment to determine what is considered the Primary \textit{Salmonella} Control Area (PSCA)
  – The PSCA in nut processing facilities is the area where post-lethality treated product is exposed to the environment
  – This area is sometimes referred to as the Ready-to-Eat (RTE) area, the critical side of the operation, the high hygiene or high risk area

• The objective of hygiene zones is to identify areas of high and low risk to the product within the manufacturing operation

• The focus is to prevent the spread of salmonellae into the PSCA where protection of the exposed post-lethality product is critical
Hygienic Zone Assessment

• The team should conduct a hygiene zone assessment of the entire facility and create a color-coded map using the following procedure:
  – Survey the entire facility including all production areas, storage, receiving, warehousing and loading docks, employee facilities such as cafeterias, break rooms, locker rooms, washrooms, maintenance areas, offices/conference rooms and others
  – Designate the PSCA, basic GMP areas, transition areas, and non-processing areas
  – Pay particular attention to areas within the facility where ingredients, products, or the environment could be a potential source of *Salmonella* and a high potential to recontaminate post-lethality treated product
  – Also pay attention to non-process areas such as forklift charging stations, refuse/recycling areas, restrooms and others that could impact the PSCA
Conceptual Plant Layout With Different Hygiene Zones

- Offices
- Employee Welfare
- Raw Material Receiving/Storage
- Hallway
- Finished Product Warehouse/Shipping
- Packaging
- Post - Roast
- Roast
- Mixing and Other Pre-Roast Steps

- PSCA (Primary Salmonella Control Area)
- Basic GMP area
- Non-process areas

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Sampling Locations – The PEM Zoning Concept

• Once the team has mapped out the hygiene zones, it is now time to select the specific sampling sites within each area.

• It is often useful to use the PEM zoning concept in order to aid in site selection and in tracking environmental data.
  – The PEM zoning concept is different than mapping hygienic zones within the facility.

• In the PEM zoning concept the plant operations are divided into four zones based on level of risk.
PEM Zone Definitions

• **Zone 1** – Areas in the plant that are direct product contact surfaces after the lethality or microbial reduction step (e.g. roaster) and before the product is sealed in the primary package
  
  – If there is no lethality step in the process, Zone 1 sites are those where the product is exposed to plant equipment and environment prior to sealing in the primary packaging

  ✓ Conveyor belts/buckets
  ✓ Utensils
  ✓ Employee hands (if touching product)
  ✓ Slicers/dicers
  ✓ Product hoppers/bins/bin liners
  ✓ Discharge Chutes
  ✓ Fillers
PEM Zone Definitions

- **Zone 2** – Non-product contact areas in the plant that are closely adjacent to product contact surfaces
  - ✓ Equipment framework
  - ✓ Drip shields/housings
  - ✓ Control panels/buttons
  - ✓ Overhead pipes directly over zone 1 surfaces
  - ✓ Computer screens
  - ✓ Maintenance tools
PEM Zone Definitions

- **Zone 3** – Non-product contact surfaces that are in open post-lethality product processing areas, but no closely adjacent to zone 1 surfaces
  - Zone 3 surfaces have the possibility of leading to product recontamination
    - Floors, walls, ceilings
    - Hoses
    - Drains
    - Condensate drip pans
    - Trolleys, forklifts, walk-alongs, carts
    - Floors, walls, ceilings
    - Hoses
    - Drains
    - Condensate drip pans
    - Trolleys, forklifts, walk-alongs, carts
    - Trash containers
    - Pallets
    - Foot baths/mats
    - Brooms/mops
    - Toolboxes
PEM Zone Definitions

- **Zone 4** – Areas remote from post-lethality product processing areas
  - Zone 4 areas if not maintained in good hygienic condition can lead to cross-contamination of zone 1 – 3 areas (PSCA)

  - Hallways
  - Loading docks
  - Bathrooms
  - Locker rooms
  - Employee cafeteria/break rooms
  - Coolers/freezers
  - Maintenance shop
  - Office areas
Sampling Locations – The Zoning Concept

Zone 1
Product Contact Surfaces
(fillers, hoppers, screens, conveyer belts, air blowers, employee hands)
Sampling Locations – The Zoning Concept

**Zone 1**

*Product Contact Surfaces*
(fillers, hoppers, screens, conveyor belts, air blowers, employee hands)

**Zone 2**

*Non-Product Contact Surfaces*
(framework, refrigeration units, equipment housing)
Sampling Locations – The Zoning Concept

Zone 1
Product Contact Surfaces
(fillers, hoppers, screens, conveyer belts, air blowers, employee hands)

Zone 2
Non-Product Contact Surfaces
/framework, refrigeration units, equipment housing

Zone 3
Other Areas within RTE Room
(air return covers, phones, hand trucks, forklifts, drains)
Sampling Locations – The Zoning Concept

Zone 1
Product Contact Surfaces
(fillers, hoppers, screens, conveyor belts, air blowers, employee hands)

Zone 2
Non-Product Contact Surfaces
(framework, refrigeration units, equipment housing)

Zone 3
Other Areas within RTE Room
(air return covers, phones, hand trucks, forklifts, drains)

Zone 4
Areas Outside of RTE Room
(locker rooms, cafeteria, hallways, loading dock, maintenance areas)
PEM Sampling and Testing Methods

• There are a myriad of sampling and testing methods that can be employed for your PEM program

• Recommended sampling methods include:
  – Surface sampling using sponges/swabs
  – Product residue scrapings/fines/dust samples
  – Water/rinse samples
  – Air samples

• Generally, a comprehensive, aggressive PEM program uses a combination of these sampling methods
PEM Sampling and Testing Methods

- There are two general categories of test methods that you can use for your PEM program
  - Testing for the specific target pathogen (*Salmonella* spp.)
  - Testing for indicators for the potential presence of salmonellae

- There are a number of indicator tests that can be used for PEM programs in nut processing operations
  - Coliforms/*Escherichia coli*
  - Total *Enterobacteriaceae* counts (TEB counts) which are superior to the coliform group as an indicator of sanitation

- Another indicator that is used in the food industry as a quality indicator is the Aerobic Plate Count (APC)
  - APC’s cannot be used as a safety indicator for pathogens because in almost all cases there is no correlation
PEM Sampling and Testing Methods

- Environmental testing for salmonellae is normally done in zones 2, 3, and 4
- Zone 1 sites are normally tested for indicators such as TEB counts
  - Only under special circumstances are zone 1 surfaces sampled for salmonellae such as investigational sampling due to a potential contamination event such as a roof leak or a finished product positive result
  - Any zone 1 testing for salmonellae necessitates a stringent product hold and release program until results are cleared
Sampling Procedures

- Sampling procedures and techniques should be conducted by properly trained and qualified individuals.

- When testing equipment and environmental surfaces for salmonellae, it is important to sample as large an area as reasonably possible.
  - Typically, a range of 40 inches² to 400 inches² should be sampled, if possible.

- If sanitizer is used as part of the normal sanitation procedure in the plant, then sponge/swab samples should be placed in buffer with neutralizing buffer (e.g. D/E neutralizing buffer).

- Sample collection should proceed from zone 1 to zone 2 to zone 3 to zone 4 sites.
Sampling Procedures

- When zone 1 sites are sampled with pre-moistened sterile sponges, the site after sampling should be wiped down with an alcohol-based sanitizer (e.g. Eco-Wipe™)

- A negative control sample should be included with each batch of environmental samples taken
  - Remove a sterile sponge/swab from its container with sterile gloves and then replace it bag into the bag or container
  - It should be coded such that the testing laboratory does not know that it is a negative control sample
Sampling Procedures

- When conducting sampling of zone 1 sites, if a sponge is used, an area of 200 inches$^2$ should be sampled
  - If using a swab, sample an area of 40 inches$^2$
  - A non-porous plastic template may be used to facilitate accurate coverage of an area
    - The template, if used, must be thoroughly sanitized between sampling sites
  - Counts are expressed as CFU/200 in$^2$ or CFU/40 in$^2$
  - If it is not possible to sample a 200 inch$^2$ area, then sample as much of the area as reasonably possible
    - The counts per unit area must be adjusted if that is the case or counts expressed as CFU’s per sponge or swab
Selection of Test Methods

- It is highly recommended that you use an official or industry-recognized method for test methods such as
  - FDA’s Bacteriological Analytical Manual (BAM)
  - ISO 6579 methods which are considered official methods in Europe, but increasingly recognized around the world
  - APHA’s Compendium of Methods for the Microbiological Examination of Foods
  - AOAC International’s Official Methods of Analysis

- Whatever method is selected, it is absolutely imperative that you validate the method on your samples, for your specific applications
Selection of Test Methods

- There are a myriad of rapid methods available for the detection of salmonellae in environmental, ingredient, and in-process/finished product samples
  - Many of these methods are immunological-based methods such as ELISA’s, modified cultural methods, or genetic-based methods such as RT-PCR
  - Each of these methods has advantages and disadvantages and must be carefully evaluated and validated for your applications
  - A validated rapid method is usually considered a screening method, where negative methods are accepted as such, but positive results need confirmation (either cultural or by some other recognized method)
Selection of Test Methods

• Compositing environmental samples by combining multiple sponges/swabs into one pre-enrichment sample should never be done
  – This can lead to a high risk of false negative results

• Environmental samples may be pooled by combining up to 10 post-enriched samples into one sample to run a rapid method such as PCR or ELISA
  – An AOAC – RI approved system (Pathatrix® Auto) by Matrix MicroScience can be used to pool PEM samples
  – As with any method this technology must be properly validated in your laboratory for your applications before it can be routinely implemented
Selection of Test Methods

• It is highly recommended that all *Salmonella* isolates from your PEM program be serotyped and characterized by a genetic typing method such as PFGE, ribotyping, or other validated and recognized method
  
  – Typing methods are very useful in troubleshooting and tracking data from your PEM program
  
  – Genetic typing “maps” can be developed showing “hot spots” or problem areas in the plant

• It should be understood that multiple strains of salmonellae have been isolated from raw nuts and from production areas
  
  – Therefore, the presence of one strain of *Salmonella* in product and a different strain in the production environment does not necessarily mean they have no commonality
Selection of Test Methods

• If your operation does not have its own microbiological testing laboratory you should use a reputable accredited independent testing laboratory.

• There are number of resources available to help you choose an accredited laboratory that is right for you:
  - AOAC’s Analytical Laboratory Accreditation Criteria Committee (ALACC) has published guidelines for “Laboratories Performing Microbiological and Chemical Analyses of Food and Pharmaceuticals” (ALACC Guide) which is ISO 17025 based (http://www.aoac.org/accreditation/faq2.htm)
  - American Association for Laboratory Accreditation (A2LA) (http://www.a2la.org/appsweb/food.cfm)
  - American Council of Independent Laboratories (ACIL) (http://www.acil.org)
PEM Sampling Frequency

• The number and location of environmental samples is determined by the risk levels inherent to the product and process
  – Areas with water use, high traffic patterns, history of positive pathogen results and areas where microbiologically sensitive raw materials are handled or stored should be sampled at a higher frequency
  – Focus should be given to post-lethality treated open product areas (PSCA) since this is where the risk of product recontamination is the highest
  – Sample sites should be identified and rotated on a weekly basis according to shift and day of week
  – Zone 4 sites should be rotated so that all sites are covered within a quarter
Number of PEM Samples

- The overall number of PEM samples taken each week depends on the size of the facility and on the historical data from the facility.

- The sampling plan must be flexible to allow for additional samples to be taken, as determined by the team.
  - “Follow the data”

- The number of zone 1 samples is line dependent and is determined by the purpose of the sampling (e.g. investigational, validation, or verification).

- In general, a greater number of zone 2 and 3 samples are taken than in zone 4 areas.
  - Generally, 10 – 15 samples are taken in zones 2 and 3 each week and 5 -10 in zone 4 areas per month, depending on the size of the facility.
## Summary of PEM Program Sampling

<table>
<thead>
<tr>
<th>Zone</th>
<th>Sampling Sites</th>
<th>Microbiological Test</th>
<th>Minimum Sampling Frequency</th>
<th>Typical Number of Samples</th>
</tr>
</thead>
<tbody>
<tr>
<td>I</td>
<td>Direct or indirect product contact surfaces</td>
<td>Indicator organisms for salmonellae (e.g. TEB Counts)</td>
<td>Weekly, post-cleaning, prior to start-up and as needed for investigational, validation and/or verification purposes</td>
<td>Line and situational dependent</td>
</tr>
<tr>
<td>II</td>
<td>Environmental surfaces immediately adjacent to product contact surfaces</td>
<td><em>Salmonella</em></td>
<td>Weekly</td>
<td>10 - 15</td>
</tr>
</tbody>
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</tr>
</thead>
<tbody>
<tr>
<td>III</td>
<td>Environmental surfaces further removed from product contact surfaces in open product areas</td>
<td>Salmonella</td>
<td>Weekly</td>
<td>10 - 15</td>
</tr>
<tr>
<td>IV</td>
<td>Areas remote from the processing area (Primary Salmonella Control Area)</td>
<td>Salmonella</td>
<td>Monthly</td>
<td>5 - 10</td>
</tr>
</tbody>
</table>
Establishing Your Baseline

- Once potential areas for sampling are identified, it is useful to conduct preliminary intensive investigational sampling with the purpose of find salmonellae if present.

- In this preliminary investigational phase, samples are collected at a much higher frequency than is done for the ongoing PEM program:
  - It is not uncommon to take 25 – 50 samples or more per zone daily for the first month (rotating shifts in a multiple shift operation) and then moving to weekly with the same number of samples for the next 2 – 5 months.

- Zone 1 sites are typically tested for TEB counts pre-operationally, before sanitizing, prior to start-up of the production line as a measure of cleaning effectiveness.
Establishing Your Baseline

- Zone 1 sites should be collected individually and never compered.
- Zones 2 and 3 samples should be collected both pre-operationally and operationally for *Salmonella*.
  - Operational samples should be taken throughout the production run (e.g., just after start-up, 3–4 hours after start-up, and at the end of the run).
  - Sampling times and sites should be rotated from week-to-week.
- Zone 4 samples should be collected on a monthly basis with a focus on sites that are adjacent to the PSCA.
Establishing Your Baseline

• Once swab locations are selected, a master list can be compiled by zone throughout the facility
  – Each zone throughout the facility can be mapped for tracking purposes and entered into a master database
  – A random number generator can be used to select swab locations to be sampled each week; however, you should ensure that each location is sampled on a rotational basis such that they are sampled at least 4 times minimum within a year

• The same exact location within a zone should not be sampled each time samples are collected unless data has shown it to be a chronic problem location
  – A PEM program is dynamic and should be responsive to the data generated by sampling – “Follow the data!”
Data Interpretation and Corrective Actions

• Data from the intensive, preliminary investigational phase is used to set up the ongoing PEM program
  – If an area shows repeated positives, then that area should be considered a potential harborage niche or problem area that warrants ongoing attention

• It is critical that corrective actions be implemented in a timely manner and documented any time a *Salmonella* positive occurs

• In general, it is recommended that you proceed on the basis of a presumptive positive result from an environmental sample as if it would be a confirmed positive
  – This is the most conservative approach and helps you gain time if turns out to be a confirmed positive
Data Interpretation and Corrective Actions

- Your facility should have a pre-determined action plan that would be implemented in the event of a *Salmonella* positive result
  - The action plan should be specific for each of the four zones and include
    - Type of immediate corrective actions to be taken by zone
    - Actions to be taken to verify *Salmonella* has been eliminated from the area in question
    - A root cause analysis to find the source of the contamination so that it can be prevented in the future
Data Interpretation and Corrective Actions

• All corrective actions including additional sample results need to be properly documented
  – It is very useful to have a computer-based spreadsheet or database for tracking results and documenting corrective actions

• If a positive result is found in any sampling zone, the area need to be thoroughly examined both visually and through vector swabbing
  – Vector swabbing entails taking multiple additional samples around the initial positive site
  – Typically, 10 -15 additional sponge/swab samples are taken in a “star burst” pattern in all directions including up and down, if appropriate
  – Troubleshooting samples should always be run individually and not pooled
Vector Swabbing Schematic

Initial Positive Site
Data Interpretation and Corrective Actions

• In the event of a *Salmonella* positive, the response team should conduct an in-depth investigation looking at
  – Any maintenance disruptions/activities
  – In-plant construction
  – Unplanned down time
  – Other non-standard production activities (e.g. R&D plant trial)

• The response team should look at these factors and all relevant records and documents from last full microbiological clean-up/sanitation to the current positive finding
Data Interpretation and Corrective Actions

• Immediate actions should be taken to correct any obvious GMP or other deficiencies based on the investigation including
  – Quarantine the suspect area and limit access to minimize spread of the contamination
  – Reinforce hygienic practices among employees, outside contractors, and others and retrain in GMP’s and food safety, if necessary
  – Assess and adjust the type and frequency of cleaning/sanitation procedures, if needed
  – Eliminate sources of water and water accumulation
Data Interpretation and Corrective Actions

– Re-examine traffic patterns and re-direct, if feasible
– Audit handling practices (product, sanitation, maintenance, and material handling
– Redesign and/or perform equipment maintenance as needed
– Conduct interdictive cleaning such as floor scrubbing and sanitation or cleaning of overhead pipes/equipment

• It would not be unexpected to occasionally find a *Salmonella* positive in zone 4 areas

• A zone 3 positive in the absence of zone 2 positives is an early indication that cleaning and sanitation program needs to be more robust
Data Interpretation and Corrective Actions

• If vector samples test positive for *Salmonella* in any zone, then additional samples must be taken to define the scope of the problem

• Aggressive corrective actions must be taken to eliminate the problem

• The following steps should be taken as part of the root cause analysis
  – Map the locations of positive samples on a facility design diagram to help define the scope of the problem
  – Implement daily vector sampling of the environment until the situation is corrected
  – Restrict traffic flow in these areas to the extent possible
Data Interpretation and Corrective Actions

– Visually inspect areas for potential harborage sites and intensify cleaning efforts in these areas

– Reinforce GMP and food safety practices with line operators and other personnel

– Visually monitor handling practices and make adjustments where needed

– Scrutinize equipment cleaning and preventative maintenance practices and modify if necessary

– Repair structural damage (e.g. floors, walls, other structures)

– Redesign and/or perform equipment maintenance as needed

– Zone 1 sampling or finished product testing may need to be implemented or intensified in the event of persistent zone 2 positives
Data Interpretation and Corrective Actions

• In extreme cases, where a hot spot cannot be eliminated or contained, serious consideration must be given to taking that production line or piece of equipment out of service
  – That area should be physically segregated from the rest of the plant until a permanent solution can be found

• When using a quantitative indicator such as TEB or coliform counts, none of these organisms should be present on equipment after cleaning and sanitation activities
Plant Construction, Equipment Installation, Major Repairs

- It is well-documented that activities such as plant construction, equipment installation, or major repair work can lead to increased recontamination risk and special precautions must be taken
  - Installing temporary control barriers such as temporary walls, ceiling to floor plastic curtains, or other suitable containment
  - Modifying traffic flow to minimize risk of spreading contamination
  - Increasing the amount of cleaning and sanitation
  - Reinforcing GMP and hygiene practices with employees and, especially, outside contractors
  - Clean and sanitize used equipment to be installed outside of the plant
  - Adjust airflow and air pressure if needed to minimize airborne transmission of dust
Plant Construction, Equipment Installation, Major Repairs

- Sampling of the environment for *Salmonella* should be performed during construction or other major activities at an increased frequency and number to ensure that no problems are being created.

- Sampling sites and frequency should be determined by the team based on:
  - Location of construction or other activities
  - Type of construction or activity (e.g. demolition, installation, major repair, material removal)
  - Time duration of the activities
  - Types of environmental controls implemented
Plant Construction, Equipment Installation, 
Major Repairs

• Once construction or major repairs are completed, the area must be thoroughly cleaned and sanitized using the principles of top-down cleaning

• Verification of cleaning/sanitation effectiveness must performed by intensively sampling the area for *Salmonella* before it is released for production activities
  – This often entails taking hundreds of sponge/swab samples of the environment in the vicinity of the construction
  – If positive results are obtained, then the area must be re-cleaned and re-sanitized and re-sampled until negative results are obtained for three consecutive samplings
Questions?
Thank you!

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